

**Department of Health Professions**

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# **Virginia Board of Pharmacy Law Update**

VPhA Annual Meeting  
August 7, 2012

Caroline D. Juran, Executive Director



# Current Board Members

- David C. Kozera, Chairman
- Jody H. Allen, Vice-Chairman
- R. Crady Adams
- Dinny Li (citizen)
- Empsy Munden
- Robert M. Rhodes
- Ellen B. Shinaberry
- Pratt P. Stelly (citizen)
- Rebecca Thornbury
- Cynthia Warriner



# Program Objectives

- Briefly review new laws which may impact the profession of Pharmacy
- Provide status of proposed regulations
- Review frequently cited deficiencies during routine pharmacy inspections
- Highlight concerns regarding trend for prescriptions from out-of-state prescribers for patients not residing in Virginia



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# New Laws Resulting from 2012 General Assembly that may Affect Pharmacy



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# NPLEx

- HB 1161 and SB 294
- Requires State Police to enter into MOU for a real-time electronic recordkeeping and monitoring system for sale of OTC ephedrine or related compounds (pseudoephedrine)
- Pharmacies and retailers will be required to use NPLEx by January 1, 2013
- Emails and faxed letters from the State Police recently sent to all pharmacies and retailers



# Prescription Monitoring Program

- HB 347 and SB 321
- Requires dispensers to report method of payment
- Grants access to federal law-enforcement agencies with authority to conduct drug diversion investigations
- Allows unsolicited reports of potential misuse to the State Police for purpose of investigation
- Allows prescribers to have unlimited number of delegates for accessing PMP



# Epinephrine in Public Schools

- HB 1107 and SB 656
- Requires local school boards to adopt and implement policies for possession and administration of epinephrine in every school
- School nurse or trained school board employee may administer epinephrine.



# Epinephrine in Public Schools

- Pharmacies may distribute epinephrine via invoice to the nurse or trained employee at the address of the school.
- Advisable that pharmacies receive some type of assurance that employee requesting epinephrine is authorized to administer the drug.





# Carisoprodol

- Federally placed in Schedule IV as of January 11, 2012, therefore, should have been inventoried at that time.
- HB 1140
- Added to Schedule IV in state law.
- Include on subsequent PIC change of inventories and biennial inventories.



# Synthetic Cannabinoids and Bath Salts

- More synthetic cannabinoids, AKA K-2 and Spice, and “bath salts” placed into Schedule I
- Increased criminal penalties associated with possessing, manufacturing and distributing these drugs
- Psychoactive substances sold in tobacco shops, adult stores, etc. and online



# Synthetic Cannabinoids and Bath Salts

- Often marketed as incense or plant food
- Addictive, dangerous, more powerful than other highs
- Deceptive marketing particularly harming young people
- Resulting in health problems and even death



# Nurse Practitioners

- HB 346 amended §54.1-2957, §54.1-2957.01
- Eliminated supervisory language
- Shall practice as part of a patient care team
- “Patient care team” means a multidisciplinary team of health care providers actively functioning as a unit with the management and leadership of one or more patient care team physicians for the purpose of providing and delivering health care to a patient or group of patients.”



### Nurse Practitioners, cont.

- No requirement for physician to regularly practice at the same location
- Shall maintain collaboration and consultation through written practice agreement with at least one physician
- Collaboration and consultation may be via telemedicine
- Ratio increased from 4:1 to 6:1
- Periodic review of patient records, no requirement for site visits



### Nurse Practitioners, cont.

- Physician may require NP be covered by a professional liability insurance policy with limits equal to current limitation on damages
- Practice agreements shall include provision for appropriate physician input in complex clinical cases, patient emergencies, and for referrals.



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# Proposed Regulatory Action



# 18VAC110-20-490 Automated dispensing devices

- Proposed regulatory changes adopted by Board in June 2012
- Resulted from Board receiving 3 petitions for rulemaking
- Will eliminate some manual auditing processes if technology used which accomplishes task and clarifies language
- Opportunity to submit public comment once Governor approves publishing of proposed regs





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# 18VAC110-20-355 Automated Counting Devices

- Public comment period closed April 25, 2012
- Proposed regulatory changes to be adopted by Board in October 2012.
- May relax current requirement for running devices dry every 60 days when containing multiple lots of drug.
- Opportunity to submit public comment once Governor approves publishing of proposed regs



# §54.1-3434.03 Continuous Quality Improvement Program

- Law requires pharmacies to comply with regs that provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors
- Pharmacies reporting to a patient safety organization are deemed in compliance with law



# §54.1-3434.03 Continuous Quality Improvement Program

- Subjects included in proposed emergency regulations:
  - Definition of “dispensing error”
  - Requirement to report dispensing error to pharmacist on-duty
  - Requirement to initiate documentation of error
  - Requirement to analyze error, assess cause recommendations for changes
  - Allowance to rid of documentation after Q/A performed
  - Requirement to maintain record indicating dates when Q/A performed and confirmation that action was taken



# §54.1-3434.03 Continuous Quality Improvement Program

- Subjects included in proposed emergency regulations:
  - Requirement that patient safety organization be credentialed by Agency for Healthcare Research Quality
  - Definition for “actively reports” – may mean reporting all dispensing errors to PSO weekly
- Emergency regulations awaiting Governor’s signature.



# §54.1-3434.03 Continuous Quality Improvement Program

- For 6 months from date authorizing the publishing of the emergency regulations, inspectors will cite non-compliance as a comment only on a routine pharmacy inspection and will not impose a monetary penalty.



# On-hold Prescriptions

- September 2010 - Board reviewed a petition for rulemaking to allow prescriptions to be filed chronologically by date of initial dispensing or initial entry into the computer
- Current rule potentially requires on-hold prescription to be moved by date of initial dispensing
- Board denied petition, but agreed to research issue to gather more information



# On-hold Prescriptions

- Surveyed states; only 2 have rules but concerns exist
  - By not requiring data entry of on-hold prescriptions, prescriptions can be lost or stolen
  - No pharmacist verification of data entry may lead to dispensing errors
  - Current filing requirement may be burdensome
- NOIRA adopted and published



# On-hold Prescriptions

- Proposed regulations require:
  - Filing of prescription by date of initial dispensing or date of initial entry into automated data processing system
  - Documentation that pharmacist verified accuracy of data entry
  - Data entry of on-hold prescription must occur





# On-hold Prescriptions

- Proposed regulations require:
  - Pharmacist dispensing on-hold prescription must perform prospective drug review
  - data entry must be deleted if patient requests on-hold prescription back prior to dispensing
- Final proposed regulations awaiting Governor's signature.



# Working Conditions

- Petition for rulemaking received in February 2012
- Requests Board to implement rules similar to WV and NC to restrict number of continuous hours a pharmacist may work and require meal breaks
- Board received 20 comments, all but one in full support
- Board adopted NOIRA in June



### Working Conditions

- Once approval is received to publish the NOIRA, will have another opportunity to submit public comment
- Currently in the Secretary's office for review



# Frequently Cited Deficiencies During Routine Pharmacy Inspections



# Major Deficiencies Commonly Cited

- Monthly perpetual inventory of Schedule II
- Inadequate alarm coverage or no back-up
- No incoming PIC inventory
- Pharmacists not checking repackaging, compounding
- No annual training documentation for media-fill testing
- Biennial inventory



# Major Deficiencies Commonly Cited

- Unregistered pharmacy technicians
- Refrigerator/freezer temperature



# Perpetual Inventory (Major #15)

- Monthly perpetual inventory not being maintained as required, to include not accurately indicating “physical count” on-hand at time of performing inventory or not noting explanation for any difference between “physical count” and “theoretical count”;
- \$250
- Guidance Document 110-16



### Alarm (Major 9a)

- Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.
- \$250





# PIC Inventory (Major 14)

- No incoming change of PIC inventory taken within 5 days or substantially incomplete, i.e., did not include all drugs in Schedules II-V
- \$500



# Pharmacist Checking (Major 20)

- Pharmacist not checking and documenting repackaging, compounding, or bulk packaging



### Media-fill Testing (Major 26)

- Annual (12 months + 30 days) training documentation involving media-fill tests for low and medium-risk levels not maintained for > 30% of individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs >45 days after receipt of a failed media-fill test
- \$500



### Biennial Inventory (Major 13)

- No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V
- \$500
- Guidance Document 110-16



# Unregistered Pharmacy Technicians (Major 3)

- Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months
- \$250
- Guidance Document 110-20



# Refrigerator/Freezer (Major 8)

- Refrigerator/freezer temperature out of range greater than  $\pm 4$  degrees
- \$100; drugs may be embargoed



# Commonly Cited Minor Deficiencies

- Inventories missing required information
- No documentation for partial-filling
- Improperly storing emergency key/alarm code
- Expired drugs
- Refrigerator/freezer within range, but no thermometer or non-functioning



# Inventories (Minor 13)

- Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate





# Partial Filling (Minor 19)

- Not properly documenting partial filling
- Guidance document 110-22
  - clarifies how dispensing records should be maintained in various practice scenarios and are used to identify pharmacist responsible for dispensing error



## Emergency Key and Code (Minor 8)

- Emergency access alarm code/key not maintained in compliance



# Expired Drugs (Minor 9)

- Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)



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# Repackaging Records/Labeling (Minor 27)

- Repackaging records and labeling not kept as required or in compliance



# Thermometer (Minor 5)

- No thermometer or non-functioning thermometer in refrigerator/freezer, but within range, +/-4 degrees



# Concerning Trends



# Prescription Validity

- Prescriptions being received in VA pharmacies from out of state prescriber and patient resides in a third state
- June Board e-newsletter article
- Use professional judgment, taking “red flags” into consideration



# Prescription Validity

- Possible “red flags”:
  - patients who reside in another state are routinely returning to the Virginia pharmacy presenting prescriptions for multiple controlled substances, such as oxycodone and benzodiazepines, written by out-of-state prescribers;
  - upon return to the Virginia pharmacy, the patient is accompanied by an increasing number of friends with prescriptions;





# Prescription Validity

- Possible “red flags”:
  - multiple patients all present identical or similar prescriptions from the same out-of-state prescriber;
  - the patients pay for the prescription using cash or credit card – there is no third-party billing; and
  - the patient who resides in another state may simply justify having the prescriptions dispensed in Virginia because it is cheaper than in his or her home state.



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# Advertisements for Canadian Pharmacies

- Recent advertisements on radio, in newspaper, and in mailings
- Pharmacy located outside US ineligible for licensure as pharmacy, therefore violation of law to ship drugs to Virginia resident
- Known concerns exist for rogue drug outlets purporting to be Canadian pharmacies
- May be selling drugs that are counterfeit, contaminated, or otherwise unsafe.



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# Advertisements for Canadian Pharmacies

- NABP reviews internet sites and maintains a “Recommended” and “Not Recommended” list on [www.nabp.net](http://www.nabp.net) (may access on BOP homepage)
- NABP reports “of the over 10,000 Internet sites reviewed, NABP found that 97% of the sites fall in the Not Recommended category”
- Board sent letters to identified radio stations, newspaper, Virginia Press Association, and Virginia Association of Broadcasters identifying possible public safety concerns and illegal activity



# Prescription Drug Abuse

- In 2010, 7 million people aged 12 or older used prescription drugs non-medically. [“Results from the 2010 National Survey on Drug Use and Health,”](#) Substance Abuse and Mental Health Services Administration (September 2011).
- Abuse is leading to an increase in opiate overdoses, but in the past opiate overdoses were most often due to heroin use. Abuse of prescription pain pills is a growing problem with a growing number of fatalities. [“Epidemic: Responding to America’s Prescription Drug Abuse Crisis”](#) (PDF), Office of National Drug Control Policy, April 2011.



# Prescription Drug Abuse

- “Almost a third (32%) of teens say they abuse prescription painkillers because they believe there are fewer side effects than street drugs.” [“Prescription for Danger: A report on the troubling trend of prescription and over-the-counter drug abuse among the nation’s teens,”](#) (PDF) from the Office of National Drug Control Policy (January 2008)

Source: [www.awarex.org](http://www.awarex.org)



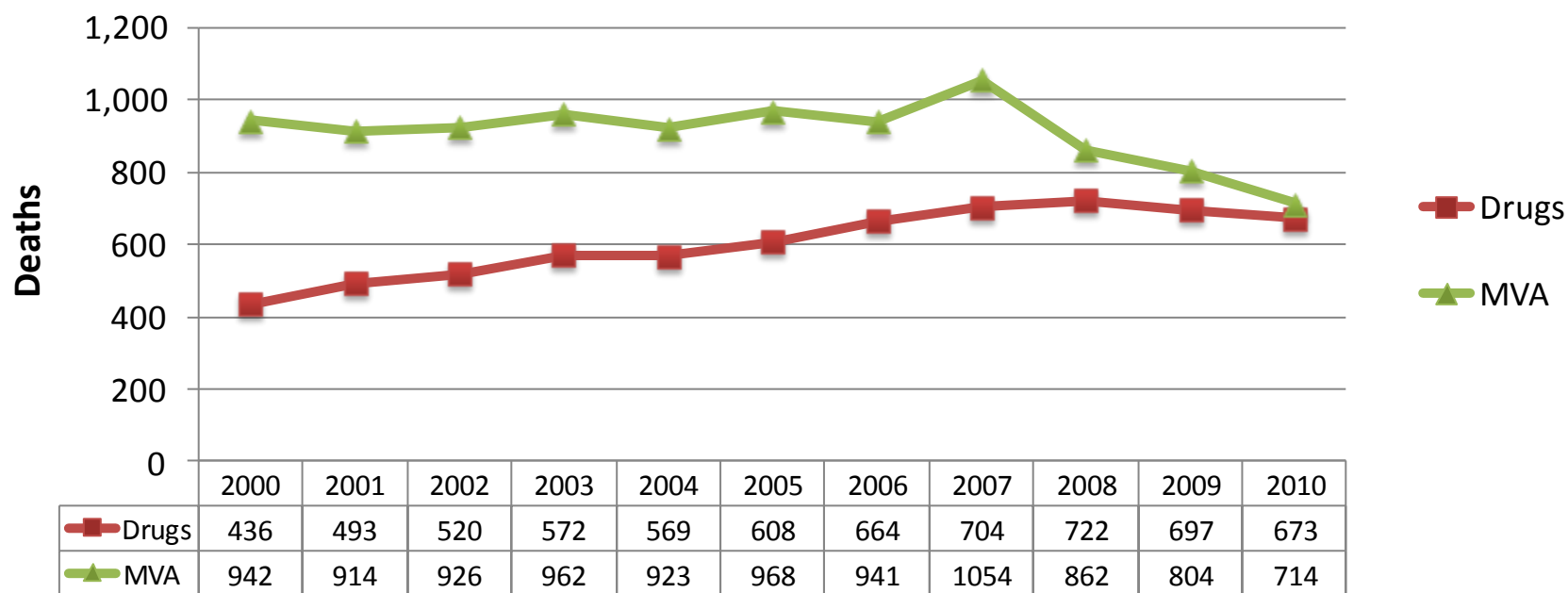
# Prescription Drug Abuse

- “More than three in five teens say prescription pain relievers are easy to get from parent’s medicine cabinet...” [“Prescription for Danger: A report on the troubling trend of prescription and over-the-counter drug abuse among the nation’s teens”](#) (PDF) from the Office of National Drug Control Policy (January 2008)



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## Drug and Motor Vehicle Deaths of Virginia Residents 2000-2010



Source: VDH, Division of Health Statistics, September, 2011



# Prescription Drug Abuse

- The White House plan to fight prescription drug abuse, [“Epidemic: Responding to America’s Prescription Drug Abuse Crisis”](#) (PDF), emphasizes that education of parents, youth, patients, and health care providers is “a crucial first step in tackling the problem of prescription drug abuse.”





# Prescription Drug Abuse

- What can pharmacists do?
  - Get educated and educate others
  - Encourage proper use of drugs
  - Encourage patients to secure their drugs at home
  - Encourage proper disposal of drugs
  - Use the PMP to assist in ensuring validity of Rx
  - Communicate with other healthcare providers when concerns of abuse exist
  - Ensure appropriate security of drugs within the pharmacy



# Prescription Drug Abuse

- [www.AWARxE.org](http://www.AWARxE.org) – consumer protection organization
- <http://www.drugfree.org/> -campaign to educate teens  
Sept 23-29th
- PeerRx – National Institute on Drug Abuse (NIDA) – educates teens on prescription drug abuse
- Consumer medication disposal – Guidance from ONDCP, US Fish and Wildlife/APhA/PhRMA, and FDA found on Board Website
- Local/national drug take-back events – manual for localities to hold take-back events, “Holding a Successful Prescription Drug Take-Back Event”, found on Attorney General’s Website



# Prescription Drug Abuse

- Next DEA Take-Back Event
  - September 29, 2012, 10 AM - 2 PM.



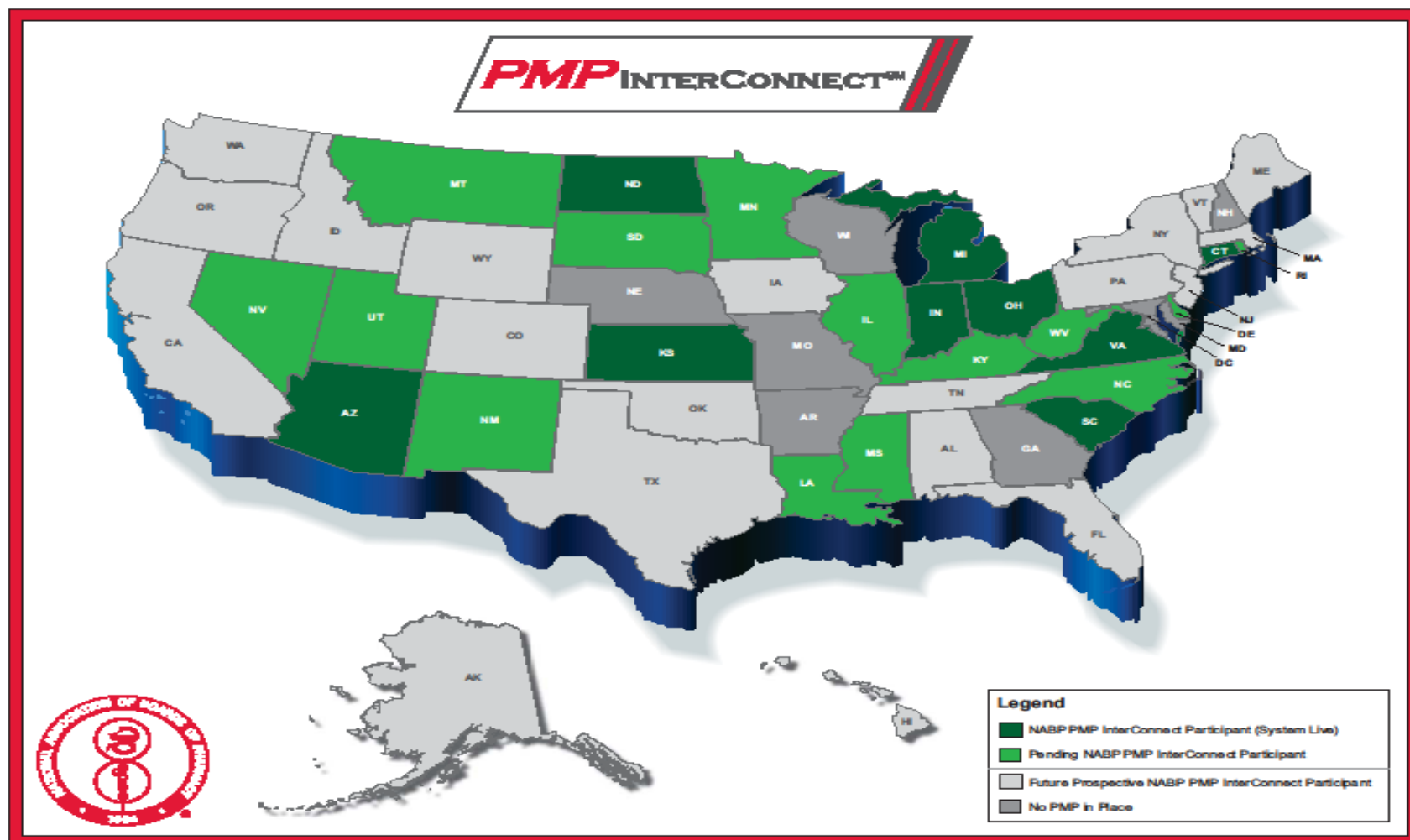
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# Miscellaneous Topics



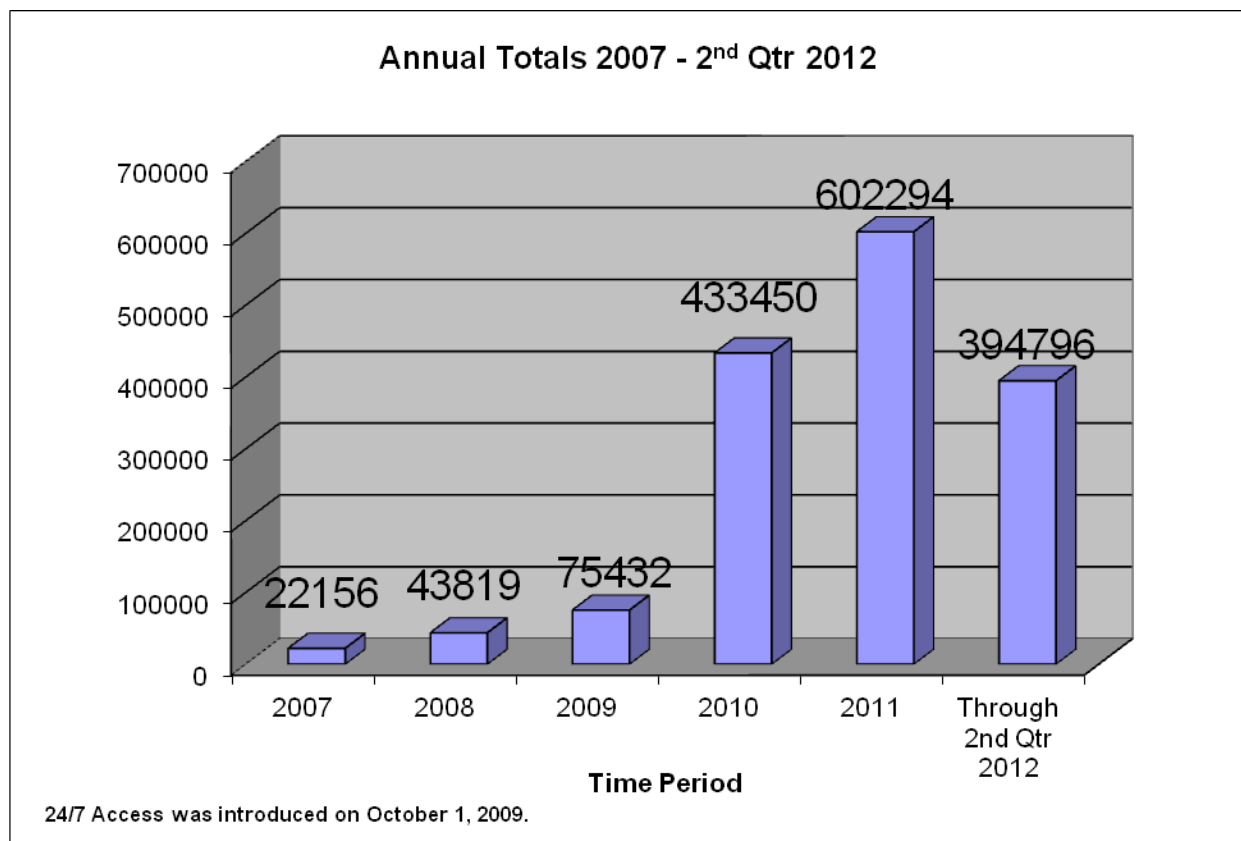
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# Program Statistics





# Pharmacy Scope of Practice Review

- Regulatory Research Committee of the Board of Health Professions held public hearing on July 23, 2012
- Reviewing pharmacists' scope of practice
- Accepting written public comment until August 17, 2012



# Pharmacy Scope of Practice Review

- Information regarding public hearing and call for public comment may be accessed at <http://www.dhp.virginia.gov/bhp>
- BHP will review pharmacy technicians' scope of practice in near future





# Board of Pharmacy Full Board Meeting

- Date has been changed to October 1, 2012



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- Board of Pharmacy website:  
[www.dhp.virginia.gov/pharmacy](http://www.dhp.virginia.gov/pharmacy)
- Email : [pharmbd@dhp.virginia.gov](mailto:pharmbd@dhp.virginia.gov)



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Questions??